



[Billing Code 6355-01-P]

CONSUMER PRODUCT SAFETY COMMISSION

Strong Sensitizer Guidance

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of availability.

SUMMARY: The U.S. Consumer Product Safety Commission (CPSC or Commission) is announcing the availability of a document prepared by CPSC staff titled, “Strong Sensitizer Guidance.” This guidance document is intended to clarify the “strong sensitizer” definition, assist manufacturers in understanding how CPSC staff would assess whether a substance and/or product containing that substance should be considered a “strong sensitizer,” and how the Commission would make such a determination. The staff guidance document is available on the Commission’s website and from the Commission’s Office of the Secretary.

ADDRESSES: The guidance document is available from the Commission’s website at <http://www.cpsc.gov/Global/Regulations-Laws-and-Standards/Regulated-Products-Rules/strongsensitizerguidance.pdf>. Copies may also be obtained from the Consumer Product Safety Commission, Office of the Secretary, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone 301-504-7923.

FOR FURTHER INFORMATION CONTACT: Joanna Matheson, Ph.D., Project Manager, Office of Hazard Identification and Reduction, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone (301) 987-2564; jmatheson@cpsc.gov.

SUPPLEMENTARY INFORMATION: Elsewhere in this issue of the Federal Register, the Commission is publishing a notice of proposed rulemaking for the purpose of revising the supplemental definition of “strong sensitizer” found at 16 CFR 1500.3(c)(5). The Commission is proposing to revise the supplemental definition of “strong sensitizer” due to advancements in the science of sensitization that have occurred since the current supplemental definition of “strong sensitizer” was promulgated in 1986. Toward this end, the Commission convened a panel of scientific experts from academia, industry, and the Federal Government who evaluated the current definition in light of scientific advances in the field of sensitization and made recommendations for proposed changes to the current definition, which eliminate redundancy, remove certain subjective factors, incorporate new and future technology for determining the sensitization characteristics of substances, rank the criteria for classification of strong sensitizers in order of importance (*e.g.*, human over animal data), define criteria for “severity of reaction”, and adopt a weight-of-the-evidence approach to determine the strength of the sensitizer.

Commission staff has prepared a document titled, “Strong Sensitizer Guidelines,” which explains and clarifies each section of the proposed “strong sensitizer” supplemental definition by explaining the current scientific rationale underlying the methodologies and analysis that staff will consider when assessing whether a substance is a strong sensitizer. The CPSC expects that the guidance document will assist manufacturers and other stakeholders in understanding how CPSC staff and the Commission would assess whether a substance or product containing a substance should be considered a “strong sensitizer.” The staff guidance document is available on the

Commission's website and from the Commission's Office of the Secretary, both listed in the **ADDRESSES** section of this notice.

Dated: March 7, 2013

Todd A. Stevenson, Secretary
U.S. Consumer Product Safety Commission

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